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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,227

04/21/2006

Christian Heinis

27280U

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7590

05/28/2008

NATH & ASSOCIATES  
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EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,227	<b>Applicant(s)</b> HEINIS, CHRISTIAN	
	<b>Examiner</b> ANAND U. DESAI	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7 drawn to rRNA and mRNA is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080122</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on January 22, 2008. Claims 18 and 19 have been cancelled. Claims 1-17 drawn to a DNA species are currently pending and are under examination.

#### **Withdrawal of Rejections**

2. The rejection of claims 1 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on the amendment to the claims.

3. The rejection of claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Epstein (U.S. Patent 5,856,090) in view of Doi and Yanagawa (FEBS Lett 457(2): 227-230 (1999)) is withdrawn in view of the remarks filed January 22, 2008.

#### **Maintenance of Rejections**

##### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. In claim 1, it is unclear what is being allocated? Is the method drawn to a method of producing a nucleic acid-protein fusion and screening for a protein functional property? What is allocated in claim 1?
7. It appears claims 3-6 are improperly dependent on claim 1. How are the respective steps performed without the prior step recited in the immediately preceding claim? Suggest, adding the step c) recited in claim 2 into claim 1 or incorporating the steps into each respective claim. Also, suggest removing the step letters. How can step d) be performed in claim 3, if no step c) is recited in claim 1? The same logic applies for claims 4-6 with respect to lettered steps.
8. The dependent claims are rejected for depending on a rejected claim 1 and failing to cure the indefiniteness.

***Claim Rejections - 35 USC § 112, First paragraph, Scope of Enablement***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
10. Claims 1-9 and 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a covalently bonded polypeptide with a modified DNA nucleic acid comprising a 5-fluorodeoxycytidine methyl transferase binding site, does not reasonably provide enablement for a method of producing any polypeptide-nucleic acid fusion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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The claims are rejected because of undue experimentation to practice the claimed method for the genus of nucleic acids (unmodified and chemically modified nucleic acid molecules) that could be covalently bonded with the genus of fusion polypeptides being claimed.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP § 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection. The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP § 2164.06(a). References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). However, specific technical reasons are always required.

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1) The nature of the invention: the instant claims are directed to a method for the production of a DNA nucleic acid-polypeptide fusion, wherein the polypeptide is encoded by the DNA nucleic acid sequence that is conjugated together. The claims are also drawn to a method of selection for a polypeptide based on a desired peptide function, such as binding.

3) The predictability or unpredictability of the art: & 6) The quantity of experimentation necessary: & 7.) The state of the prior art: the prior art has shown a large quantity of experimentation is often necessary to overcome the unpredictable nature of selecting a protein phenotype from a nucleic acid genotype population of species. Bertschinger and Neri disclose that to select for the proper genotype based on phenotype the water in oil emulsion should contain one chemically modified DNA molecule with a methyltransferase binding site otherwise the improper genotype maybe selected (see entire document, particularly page 706, 2<sup>nd</sup> indented paragraph on right hand side).

Therefore, the unpredictability arises due to the differing conditions of starting materials, such as the genus of nucleic acids being claimed to be covalently modified with a polypeptide (i.e. both unmodified and modified), and due to the different structures of the nucleic acids that could be covalently bonded to polypeptides.

Consequently, there would be a large quantity of experimentation necessary to determine what genus of nucleic acids, including unmodified nucleic acids can be covalently bonded with any polypeptide to isolate the proper genotype based on the phenotype.

4) The amount of direction or guidance presented: & 5) The presence or absence of working examples: the specification exemplifies the use of methyltransferase binding

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sites on chemically modified nucleic acids to conjugate polypeptides with the corresponding nucleic acid sequence that encodes the polypeptide.

8.) Level of skill in the art: the level of skill in this art is high, at least that of a doctoral scientist with several years of experience in the art.

In consideration of the Wands factors, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

### ***Conclusion***

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 23, 2008

/Anand U Desai, Ph.D./  
Patent Examiner, Art Unit 1656